

Appl. No. 10/681,639
Amendment dated April 12, 2007
Reply to Office Action

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REMARKS/ARGUMENTS

Applicant respectfully requests reconsideration of the above-identified application in view of the foregoing amendments and following remarks.

The Examiner has deemed the election requirement final in the Office Action of January 12, 2007. The Applicant has withdrawn claims 3, 4, 8, 9, 14, 19, 22, 23 and 27 to 32. Claims 1, 2, 5, 12, 13, 20, 21, 24, 25, 26 and 33-35 remain in the application and have been amended. New claims 36 to 39 been added that is supported by the description at paragraphs 42, 43 and 45 for example. Should the presently elected claims be found allowable, Applicants request that the Examiner review the claims of the other groups according to the practice of rejoinder as set forth in the MPEP and rejoin the other claims in the same application.

Claim Objections

The Examiner objected to claims 2, 5, 7, 10 to 13, 21, 24 to 26 and 33 to 35 due to a number of informalities. Claim 2 is amended to recite "The platform according to claim 1 wherein the platform flow channel has an indent...". Claim 5 is amended to recite "The platform according to claim 1 further comprising...". Claims 7, 10-13, 21, 24-26 and 33-35 are amended to replace "A" with "The". The term "such" is deleted from line 16 of claim 20.

Claims 2, 7, 11, 12, 13, 21, 25, 26, and 33 to 35 have been amended to recite "wherein".

In view of these amendments, withdrawal of these objections is respectfully requested.

Claim Rejections - 35 USC § 112

The Examiner rejected claims 1, 2, 5 to 7, 10 to 13, 20, 21, 24 to 36 and 33 to 34 under 35 U.S.C. 112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicant regards as the invention.

The Examiner contends that claim 1 is vague because it recites "a platform useful for containing". The Examiner also contends that it is unclear whether the membrane channel is the same as the platform channel. The Examiner is also unclear whether "the

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membrane" is the same as the "one or more dry porous membranes" in this claim. In the interest of clarity, the Applicant has amended claim 1 to recite "comprising". Claim 1 is also amended to refer to "membranes". Further claim 1 is amended at line 12 to recite "...the formed platform flow channel is in fluid communication with the membranes....". At line 3, the membrane channel refers to that channel present in the membranes whereas the platform flow channel is stated to be upstream of the membranes.

Claims 2, 7 and 21 are amended to positively recite the structure and thus are clearly directed to a platform or device.

Claims 5, 10 and 24 are amended to recite "further comprising...".

Claims 6 and 10 are amended to delete the term "useful".

The Examiner has also rejected claims 6 and 20 contending a number of expressions are unclear. These claims are amended to overcome the indefiniteness rejections. In view of the foregoing, the Applicant respectfully requests the Examiner withdraw the rejections to these claims.

Claim Rejections - 35 USC § 103

The Examiner has rejected claims 1, 2, 5 to 7, 10, 11, 20, 21, 24, 25, 33 and 34 under 35 U.S.C.103(a) as being unpatentable over Kang et al. (U.S. Patent 5,559,041) in view of Catt et al. (U.S. Patent 6,451,619) having regard to Yu (U.S. Patent 6,723,500). The Examiner has also rejected claims 1, 2, 5 to 7, 10, 11, 20, 21, 24, 25, 33 and 34 under 35 U.S.C.103(a) as being unpatentable over Kang et al. in view of Catt et al. having regard to Segal et al. (U.S. Patent 6,300,141). The Examiner has also rejected claims 12, 13 and 26 under 35 U.S.C.103(a) as being unpatentable over Kang et al. in view of Catt et al. further in view of Segal et al. as applied to claims 6 and 20 having regard to Freltag et al. (U.S. Patent 6,214,629). The Applicant respectfully disagrees.

The present invention is a diagnostic device for detecting at least one component in a small sample volume (from about one or few drops of whole blood). The ability to detect components in a small volume of sample is accomplished by providing a platform with a sample application means having top and bottom layers of hydrophilic surfaces to enclose and position a membrane, the top and bottom layers are brought into fixed face to face contact and form a platform flow channel and including an indent in at least one of the hydrophilic surfaces. As can be seen on page 11, paragraph 42, lines 1-2 and

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indent is provided in at least one of the hydrophilic surfaces and that the indent forms a platform flow channel which is in fluid communication with one or more dry porous membranes.

Kang et al. teach a device enclosed in casing 222 having an aperture 224 formed therein, the aperture is situated directly over reservoir pad 210 and that sample is added through aperture 224 and is absorbed by reservoir pad 210. The aperture merely serves as an opening for the sample.

Catt et al. teaches a dipstick type of assay device comprising upper and lower halves 200 and 201, respectively, to enclose and position a membrane. There is an indent in the bottom surface of the top layer, however, the indent merely serves to clamp and hold the receiving member 202 and the end 204 of the assay strip. The Applicant asserts that Catt et al. does not teach a platform flow channel formed from a top and bottom layer and in face to face contact.

Yu et al. teaches test strips with reaction zones defined by hydrophobic barriers.

The combination of these references does not provide all of the recited features of the platform of claim 1, the device of claim 6 nor the device of claim 20 (or claims dependent therefrom). The presently noted claims have a top and bottom layers that mate to form a platform flow channel at one end for the sample to enter via the sample application means. The membranes are provided enclosed between the top and bottom layers so that the sample will enter through the sample application means into the platform flow channel and then to the enclosed membranes and via the membrane channel where detection of components are accomplished. The top and bottom layers have hydrophilic surfaces that enclose the membranes. Together the structure allows the sample to flow in a continuous pathway from the sample application means to the end of the membranes. The combination of cited references does not together teach or suggest the following claimed features of claims 1, 6 or 20;

a platform with sample application means and top and bottom layers with hydrophilic surfaces to enclose and position membranes,

each of the layers having a top and bottom layer surface so that the bottom surface of the top layer and the top surface of the bottom layer are in fixed face to face contact so that the layers enclose and hold the membrane in place and form a platform flow channel upstream of the membranes

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an indent in at least one of the hydrophilic surfaces that form the platform flow channel in fluid communication with the membranes to permit the liquid sample to flow in a continuous pathway from the sample application means to the distal end of the membranes.

Again, none of the cited documents suggest the desirability of making such a combination as claimed and therefore claims 1, 6 and 20 (and claims dependent therefrom) are not obvious. Dependent claims contain the patentable features of the independent claims and therefore are unobvious in view of the combination of references asserted by the Examiner.

The Examiner also rejected claims 1, 2, 5 to 7, 10, 11, 20, 21, 24, 25, 33 and 34 under 35 U.S.C.103(a) as being unpatentable over Kang et al. in view of Catt et al. having regard to Segal et al. With respect to the Kang et al. and Catt et al. references, the Applicant has discussed these references above. With respect to the Segal et al. reference, the Applicant respectfully disagrees. Segal et al., simply discloses the use of a hydrophilic material. The other recited components of claims 1, 6 or 20 are not taught or suggested by Segal. Furthermore, Segal et al., does not suggest making any such variation to his diagnostic card device to provide the claimed invention. Thus Segal et al. fails to remedy the defects in Kang et al. and Catt et al. and therefore the combination of Kang et al. in view of Catt et al. having regard to Segal et al. fail to teach each and every element in independent claims 1, 6 and 20 and therefore cannot render the subject matter of these claims obvious. As the Examiner is aware, the cited art must disclose the desirability of making the combination. And again, the dependent claims contain the patentable features of the independent claims and therefore are unobvious in view of the combination of references asserted by the Examiner.

The Examiner also rejected claims 12, 13 and 26 under 35 U.S.C.103(a) as being unpatentable over Kang et al. in view of Catt et al. in further view of Segal et al. as applied to claims 6 and 20 having regard to Freitag et al. The Applicant respectfully disagrees. As mentioned above, neither Kang et al. in view of Catt et al. in further view of Segal et al. teach or suggest each and every element in the independent claims. Freitag et al. teach reagents for the detection of troponin I in a chromatographic assay.

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The Applicant asserts that Freitag et al. fails to remedy the defects of Kang et al. In view of Catt et al. in further view of Segal et al. with respect to the independent claims 6 and 20 and therefore cannot render the subject matter of these claims obvious. Accordingly, dependent claims 12, 13 and 26 which add additional limitations also cannot be rejected for being obvious in view of the cited references. Withdrawal of the rejection is respectfully requested.

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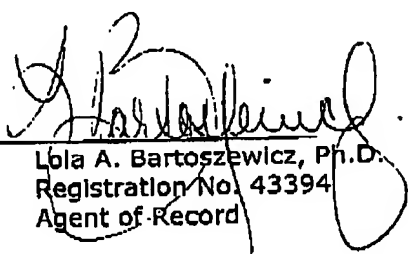
Conclusion

The Applicant requests the Examiner reconsider and withdraw all outstanding objections and rejections, enter the amendments, and pass the resulting claims to allowance.

Respectfully Submitted,
SIM & McBURNEY

LAB/KKM//ca

Encls.


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